two (52) patients and 58 lesions were evaluated by angiography and IVUS at 4 months.
MACE at four-month was 3.3 and 0 respectively and remained unchanged at one year follow-up. Four month in-stent late loss was similar in both groups: 0.36±0.30mm and 0.34±0.27mm respectively. In-segment late loss was 0.20±0.33 mm and 0.33±0.33 mm respectively. Serial IVUS analysis was available for 28 patients and 28 lesions in group A and 23 patients and 28 lesions in group B. The neointimal volume was 13.5±9.5 mm^2 and 13.5±9.5 mm^2 respectively. There was no stent thrombosis.
Conclusion: In this FIM study, implantation of the Cobra-P low dose(LD)PES with a bioabsorbable sol gel coating was proven to be feasible and safe. Minimal neointimal proliferation was observed as well as an acceptable MACE rate at 4-months and 1 year. Additional large clinical trials should be considered to confirm the promising early results.

TCT-268

Long Term Outcome Following Treatment Of Drug Eluting Stent Restenosis

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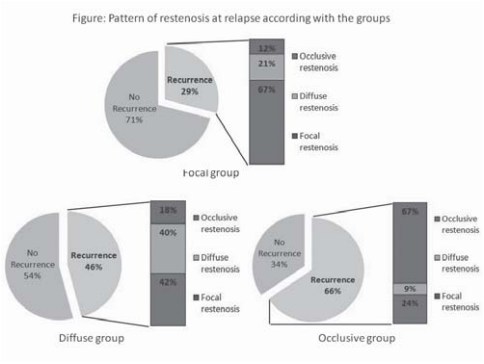
Background: Long-term outcomes following percutaneous treatment of drug-eluting stent restenosis (DES-ISR) are unclear.
Methods: Retrospective analysis of 481 consecutive de novo DES-ISR lesions (392 patients) treated percutaneously between August'02 and July'07. We divided lesions based on the pattern of restenosis: focal (305; 63.4%), diffuse (120; 24.9%), occlusive (56; 11.6%).
Results: Majority (65%) of patients had angina or ischemia on presentation and 13% an ACS. Angiographic follow-up was available in 65.5% of lesions. In comparison to the focal group (29.1%), angiographic restenosis was significantly higher in the diffuse (45.8%; p=0.007) and occlusive groups (65.6%; p<0.0001). The pattern of DES-ISR predicted the pattern of recurrence (See Figure). During a median follow-up of 2.97 years (IQR 2.37-3.89), MACE occurred in 32.8% with no differences between the focal, diffuse and occlusive (30.9%, 38.7%, 31.1%; p=0.38). Diffuse restenosis was associated with a significantly higher TLR rate compared to focal (27.1% vs. 15.8%; p=0.008). A disparity between restenosis (65.6%) and TLR (18.5%) rates for occlusive DES-ISR suggests that in the occlusive group many recurrences were not treated. Diffuse restenosis (HR 2.05, 95% CI 1.30-3.22; p=0.02) and previous CABG were the only independent predictors of TLR. For recurrent restenosis, both diffuse (HR 2.19, 95% CI 1.42-3.38; p<0.0001) and occlusive (HR 4.86, 95% CI 2.82-8.34; p<0.0001) patterns of restenosis as well as previous CABG were predictive.



Conclusions: DES-ISR identifies a high-risk cohort that is at increased risk of events, in particular repeat revascularization, during long-term follow-up. The initial pattern of restenosis is the most important predictor of recurrent restenosis or the need for subsequent re-intervention.

TCT-269

Five Years Follow-up of DIABETES Trial: The final results

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Background: The DIABETES (DIABETes and sirolimus Eluting Stent) trial is a prospective, multicenter, randomized, controlled trial aimed to demonstrate the efficacy of sirolimus-eluting stent (SES) implantation as compared to bare metal stent (BMS) in diabetic patients (pts). The aim of this study was to assess the 5-year clinical follow-up of the pts included in this trial.
Methods: From January to November 2003, 160 pts (222 lesions) were included in the trial: 80 pts were randomized to SES and 80 pts to BMS. Pts were eligible for the study if they were identified as non-insulin or insulin-dependent diabetics, with significant coronary stenoses in ≥1 vessel. There was a sub-randomization according to the type of diabetes. Dual antiplatelet therapy (aspirin indefinitely and clopidogrel for 1 year) was routinely prescribed.
Results: Five-year clinical follow-up (mean 57±18 months) was obtained in 96.2% of the patients included in the trial. The TLR rate at 5-years was still significantly lower in the SES group (7.8% vs. 37.7%, p<0.001), whereas myocardial infarction and cardiac death rates were similar between groups (5.2% vs 10.4;P=0.36), (3.9% vs 5.2%, p=1), respectively. Between 2 and 5 years very few events have been recorded. In the SES group 1 pt suffered from sudden cardiac death, this patient had stent mallaposition at 9 months and another pt presented a possible stent thrombosis 13 days after aspirin withdrawal. In the BMS group 1 pt died due to end-stage heart failure and 1 pt suffered definitive stent thrombosis. Independent predictors of MACE at 5 years were: SES implantation [0.12 (0.05-0.28);p<0.001], multivessel disease [4.3(1.4-13.06);p=0.008], multivessel stent implantation [1.94 (1.04-3.63);p=0.03], peak of CPK after the procedure [1.01(1.004-1009);p<0.001)] and creatinine levels [2.3(1.3-3.9);p=0.004].
Conclusions: SES implantation in diabetic pts continues to demonstrate the efficacy at 5 years. No safety concern has been observed in the SES group as compared to BMS group at long term follow-up.

TCT-270

Impact of Second Generation versus First Generation Drug-eluting Stents on Significant Myonecrosis following Percutaneous Coronary Intervention in Non-Acute Myocardial Infarction Patients

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Background: The effect of 2nd generation drug-eluting stents (DESs, Zotarolimus, Endeavor™/Everolimus, Promus™ or Xience™) versus 1st generation DES (Sirolimus, Cypher™/Paclitaxel, Taxus™) on significant myonecrosis following percutaneous coronary intervention (PCI) in non-acute myocardial infarction (AMI) patients (pts) is largely unknown.
Method: A total 996 consecutive non-AMI pts who underwent PCI with DESs were divided into two groups. Myonecrosis group (N=152 pts) consists of pts who had either CK-MB > 15 U/L or Trop-I > 0.3 ng/mL (3 times or more upper normal) post-PCI within 24 hours period while No-Myonecrosis group (N=844 pts) consists of pts who had CK-MB ≤15 U/L and Trop-I ≤0.3 ng/mL.
Results: A total 544 (64.5%) pts received 1st generation DESs in No Myonecrosis group whereas 34 (24.4%) pts received 2nd generation DESs in the Myonecrosis group. Pts in Myonecrosis group were found to have worse angiographic characteristics than pts in No Myonecrosis group (Table).On multivariate analysis, there was a trend toward higher incidences of significant myonecrosis in pts receiving 1st generation DESs as compared to 2nd generation DESs (OR 1.602; 95% CI 0.943-2.720, P=0.081).

Table. Variables predicting post-PCI significant myonecrosis

Variable, n (%)	No Myonecrosis Group (n=844 pts)	Myonecrosis Group (n=152 pts)	P-Value
Age	65.41±10.26	68.80±10.95	0.001
Multivessel disease	182 (21.6)	51 (33.6)	0.002
Bifurcation lesion	339 (40.2)	75 (49.3)	0.040
Ostial Lesion	213 (25.2)	55 (36.2)	0.007
Calcified Lesion	134 (15.9)	35 (23.0)	0.035
Sirolimus/Paclitaxel	544 (64.5)	118 (77.6)	0.001
Zotarolimus/Everolimus	300 (35.5)	34 (22.4)	
Echo EF (%)	55.20±7.96	52.13±10.97	0.002
Baseline CK-MB	2.76±1.58	3.76±2.44	0.002
Baseline Glucose	128.83±53.00	141.63±58.46	0.016
Baseline BNP level	542.43±2189.53	730.19±4904.83	0.008
Baseline Creatinine	0.98±0.82	1.31±1.37	0.005
Procedure time	40.66±32.42	59.20±38.38	<0.001
Lesion Length	23.57±10.23	25.35±13.76	0.047
Pre-MLD	0.59±0.38	0.52±0.35	0.002
Clopidogrel Loading Dose	344.45±170.00	315.88±178.17	0.091

Conclusion: Worse baseline angiographic and procedural features was associated with higher incidences of post-PCI myonecrosis and there was a trend toward higher incidences of significant myonecrosis following PCI with 1st generation DESs as compared to 2nd generation DESs in Non-AMI pts.

TCT-271

Cost Analysis of Four Major Drug-Eluting Stents in Diabetic Populations

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Background: Patients with diabetes are at increased risk for restenosis versus patients without diabetes. Recent studies reported differences in drug-eluting stent (DES) safety and efficacy in diabetic patients, however, there is no single trial that compares all major DES. The study objective was to combine trials and conduct a cost analysis comparing CYPHER™, ENDEAVOR™, TAXUS™, and XIENCE™ from a US payer perspective.
Methods: Upon literature review, studies were chosen that randomized two or more DES and included a diabetic subpopulation. Included studies were ISAR-DIABETES, SIRTAX, Kim 2008, DiabeDES, DES-Diabetes, ZEST, and SPIRIT IV and only diabetic patient data were analyzed. First, one-year TLR (target lesion revascularization) rates for TAXUS were derived by combining data from all trials and weighting by sample. Then, a relative risk (RR) for CYPHER vs. TAXUS was calculated by conducting a meta-analysis in RevMan (Cochrane Collaboration, 2008). For ENDEAVOR and XIENCE, RRs vs. TAXUS were available from single studies. The RRs were then multiplied by the combined TLR risk for TAXUS to estimate combined TLR risks for each stent. These imputed estimates were added to the budget-impact model, along with reported usage and reimbursement rates for diagnosis-related groups (DRGs) from the US CMS (DRG's 247-251 and 233-236). DES budgets were calculated, assuming 100% utilization for each stent and 200,000 diabetic Medicare beneficiaries receiving index PCI with DES.
Results: One-year TLR rates were approximately 3.4% for CYPHER, 7.1% for XIENCE, 7.6% for ENDEAVOR, and 8.3% for TAXUS. By substituting CYPHER instead of DES with higher TLR, results predicted annual cost savings of $144 million (vs XIENCE), $163 million (vs ENDEAVOR), and $193 million (vs TAXUS) per population, corresponding to $719, $817, and $964 per patient respectively.
Conclusions:
Pooled results showed that CYPHER has lower TLR risk in patients with diabetes compared with other major DES. When outcomes from randomized, head-head trials of diabetic patients are combined, differences in one-year TLR rates translate into large potential cost savings to the US payer. Further study is required to assess budget impact when considering safety outcomes such as stent thrombosis.

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